GE Healthcare

GE Healthcare, Surgery
384 Wright Brothers Drive
Salt Lake City, Utah 84116
U.S.A.

Certified Mail Return Receipt Requested

URGENT RECALL NOTICE

PLEASE TAKE ACTION TO INFORM ALL USERS OF THE RELEVANT SYSTEM(S) OF THESE ISSUES AND HOW TO ADDRESS THEM

January 23, 2008

To: **Director/Manager of Radiology**
Facility Administrator

Subject: **Product Safety Issues**

Affected Products: OEC® InstaTrak 3500 Plus FluoroTrak and FluoroCAT spinal applications used with Regular and Super C 9800 and 9600 C Arm systems and OEC® FluoroTrak 9800 C-arms

Our records indicate that your facility has one or more of the following GEHC OEC products:

- OEC® InstaTrak 3500 Plus Fluoro Trak and Fluoro CAT Spinal Applications used with Regular and Super C 9800 and 9600 C-arm Systems or OEC® FLuoroTrak 9800 C-arm.

GE Healthcare Surgery has identified a potential safety issue with the systems listed above.

If your facility is receiving this notification, our records indicate that your OEC® InstaTrak 3500 Plus or 9800 FluorTrak may be affected by this issue.

GEHC Surgery has identified through internal testing, issues that could impact the overall accuracy of the FluoroTrak and FluoroCAT spinal applications on the InstaTrak 3500 Plus system when used with either the 9" Regular C Arm or the "Super C" C Arm. This issue could result in an injury to the patient due to incorrect anatomical location of an instrument during a procedure.

Interim Solution:

Users are advised to stop usage of the FluoroTrak and FluoroCAT spinal applications on the InstaTrak 3500 Plus system.

NOTE:

Some customers received a communication dated March 22, 2007 indicating that a software correction to address this issue was being evaluated. After completing this evaluation, GEHC has concluded that this issue is best addressed by executing the removal of the Calibration Target Attachment for the Spinal Application.

A GE Healthcare Representative will remove this device from your facility and return it to the GE Healthcare Surgery Facility in Salt Lake City, UT. A GE Healthcare Representative will contact you to schedule this removal.

At this time, GEHC Surgery is evaluating solutions for the issues identified. Once a solution is identified a GEHC Surgery Field Service Representative will contact you to arrange for installation of the solution at no charge.

If you have any questions or concerns regarding these issues, please do not hesitate to contact the service team for further information at 800-874-7378 option 8. Information is available at this number 24 hours per day, 7 days a week.

Thank you,

Pete McCabe
President and CEO
GE Healthcare Surgery

Maria Frame
Vice President
Quality and Regulatory Affairs
GE Healthcare Surgery